

Appl. No. 10/764,177
Preliminary Amdt dated: March 28, 2005

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1 (original): An enveloped pharmaceutical composition comprising:
a first active available for immediate release; and
a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof, wherein the first and the second active are disposed on separate carriers.

Claim 2 (original): The composition of claim 1, wherein the first and second actives are enveloped in a single dose.

Claim 3 (original): The composition of claim 1, wherein the first and second actives are enveloped into a single dose.

Claim 4 (original): The composition of claim 1, wherein the first and second actives are packed into a capsule, caplet, softgel, gelcap, suppository, film, granule, gum, insert, pastille, pellet, troche, lozenge, disk, poultice or wafer.

Claim 5 (original): The composition of claim 1, wherein over 80% of the first active is released within about 60 minutes.

Claim 6 (original): The composition of claim 1, wherein immediate release is defined further as comprising release of over 90% of the first active within about 90 minutes.

Claim 7 (original): The composition of claim 1, wherein extended release is defined further as comprising release of over 80% of the second active within about 60 minutes to about 8 hours.

Claim 8 (original): The composition of claim 1, wherein extended release is defined further as comprising release of over 90% of the second active within about 90 minutes to about 6 hours.

Claim 9 (original): The composition of claim 1, wherein the first active comprises gauifenesisin.

Claim 10 (original): The composition of claim 1, wherein the first active comprises gauifenesisin DC in a powder form.

Claim 11 (original): The composition of claim 1, wherein the first active comprises 211 mg of 95% gauifenesisin.

Claim 12 (original): The composition of claim 1, wherein the second active comprises a nasal decongestant.

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Claim 13 (original): The composition of claim 1, wherein the second active comprises phenylephrine.

Claim 14 (original): The composition of claim 1, wherein the second active comprises phenylephrine as a sustained release bead.

Claim 15 (original): The composition of claim 1, wherein the second active comprises phenylephrine as a layered sustained release bead.

Claim 16 (original): The composition of claim 1, wherein the second active comprises three or more layers of phenylephrine on a bead.

Claim 17 (original): The composition of claim 1, wherein the first active is superposed on the second active.

Claim 18 (original): The composition of claim 1, comprising further one or more inactives.

Claim 19 (original): The composition of claim 1, wherein the first active for immediate release comprises a powder form and the second active comprises a beaded form.

Claim 20 (original): An enveloped pharmaceutical composition comprising:
a first active available for immediate release; and
a second active available for extended release, wherein the first active effects a physiological result that improves the physiological action of the second active upon extended release.

Claim 21 (original): The composition of claim 20, wherein the first and second actives are enveloped in a single dose.

Claim 22 (original): The composition of claim 20, wherein the first and second actives are enveloped into a single dose.

Claim 23 (original): The composition of claim 20, wherein the first and second actives are packed into a capsule, caplet, softgel, gelcap, suppository, film, granule, gum, insert, pastille, pellet, troche, lozenge, disk, poultice or wafer.

Claim 24 (original): The composition of claim 20, wherein over 80% of the first active is released within about 60 minutes.

Claim 25 (original): The composition of claim 20, wherein immediate release is defined further as comprising release of over 90% of the first active within about 90 minutes.

Claim 26 (original): The composition of claim 20, wherein extended release is defined further as comprising release of over 80% of the second active within about 60 minutes to about 8 hours.

Claim 27 (original): The composition of claim 20, wherein extended release is defined further as comprising release of over 90% of the second active within about 90 minutes to about 6 hours.

Claim 28 (original): The composition of claim 20, wherein the second active for extended

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release is selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof.

Claim 29 (original): The composition of claim 20, wherein the first active comprises gauifenesin.

Claim 30 (original): The composition of claim 20, wherein the first active comprises Gauifenesin DC in a powder form.

Claim 31 (original): The composition of claim 20, wherein the first active comprises 211 mg of 95% gauifenesin.

Claim 32 (original): The composition of claim 20, wherein the second active comprises a nasal decongestant.

Claim 33 (original): The composition of claim 20, wherein the second active comprises phenylephrine.

Claim 34 (original): The composition of claim 20, wherein the second active comprises phenylephrine as a sustained release bead.

Claim 35 (original): The composition of claim 20, wherein the second active comprises phenylephrine as a layered sustained release bead.

Claim 36 (original): The composition of claim 20, wherein the second active comprises three or more layers of phenylephrine on a bead.

Claim 37 (original): The composition of claim 20, wherein the first active is superposed on the second active.

Claim 38 (original): The composition of claim 20, comprising further one or more inactives.

Claim 39 (original): The composition of claim 20, wherein the first active for immediate release comprises a powder form and the second active comprises a beaded form.

Claim 40 (original): An enveloped pharmaceutical composition comprising:
a first active packaged so that over 90 % of the first active is released within about 90 minutes;
and
a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof, wherein over 90% of the second active is released between about 1 and 6 hours.

Claim 41 (original): The composition of claim 40, wherein the first and the second actives are disposed on separate carriers.

Claim 42 (original): The composition of claim 40, wherein the first and second actives are enveloped in a single dose.

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Claim 43 (original): The composition of claim 40, wherein the first and second actives are enveloped into a single dose.

Claim 44 (original): The composition of claim 40, wherein the first and second actives are packed into a capsule, caplet, softgel, gelcap, suppository, film, granule, gum, insert, pastille, pellet, troche, lozenge, disk, poultice or wafer.

Claim 45 (original): The composition of claim 40, wherein over 80% of the first active is released within about 60 minutes.

Claim 46 (original): The composition of claim 40, wherein immediate release is defined further as comprising release of over 90% of the first active within about 60 minutes.

Claim 47 (original): The composition of claim 40, wherein extended release is defined further as comprising release of over 80% of the second active within about 60 minutes to about 8 hours.

Claim 48 (original): The composition of claim 40, wherein extended release is defined further as comprising release of over 90% of the second active within about 90 minutes to about 6 hours.

Claim 49 (original): The composition of claim 40, wherein the first active comprises gauifenesin.

Claim 50 (original): The composition of claim 40, wherein the first active comprises gauifenesin in a powder form.

Claim 51 (original): The composition of claim 40, wherein the first active comprises 211 mg of 95% gauifenesin.

Claim 52 (original): The composition of claim 40, wherein the second active comprises a nasal decongestant.

Claim 53 (original): The composition of claim 40, wherein the second active comprises phenylephrine.

Claim 54 (original): The composition of claim 40, wherein the second active comprises phenylephrine as a sustained release bead.

Claim 55 (original): The composition of claim 40, wherein the second active comprises phenylephrine as a layered sustained release bead.

Claim 56 (original): The composition of claim 40, wherein the second active comprises three or more layers of phenylephrine on a bead.

Claim 57 (original): The composition of claim 40, wherein the first active is superposed on the second active.

Claim 58 (original): The composition of claim 40, comprising further one or more inactives.

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Claim 59 (original): The composition of claim 40, wherein the first active for immediate release comprises a powder form and the second active comprises a beaded form.

Claim 60 (original): An enveloped pharmaceutical composition comprising:
a first active available for immediate effervescent release; and
a second active for extended release in a mini-tab selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof.

Claim 61 (original): An enveloped pharmaceutical composition comprising:
a first active available for immediate release; and
a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof wherein the first and second actives are different.

Claim 62 (canceled)

Claim 63 (canceled)

Claim 62 (original): A method of loading one or more actives on a bead for extended release comprising:
adding a first active onto one or more beads with an adhesive and a sustained release coating;
and
adding a extended release coating prior to or in combination with a second active.

Claim 63 (original): The method of claim 62, wherein the adhesive comprises a pharmaceutical glaze.

Claim 64 (original): The method of claim 62, wherein the adhesive is a sustained release coating that is added prior to the addition of the first active.

Claim 65 (original): The method of claim 62, wherein the adhesive is a sustained release coating that is added concurrent with the addition of the first active.

Claim 66 (original): The method of claim 62, wherein the adhesive is a sustained release coating is about or after the addition of the first active.

Claim 67 (original): The method of claim 62, wherein the adhesive is a sustained release coating is mixed with the first active, and the mixture is added onto one or more beads.

Claim 68 (original): The method of claim 67, wherein the bead comprises a portion of a mini-tab.

Claim 69 (original): The method of claim 62, further comprising the step of adding an erosion matrix.

Claim 70 (original): The method of claim 62, further comprising the step of adding one or more inactives.

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Claim 71 (original): A method of loading an active into a mini-tab to be encapsulated for extended release, using an erosion matrix.

Claim 72 (original): A method of providing a dual-release formulation comprising: a first active in a powered form and a second active in an extended release form, wherein the first and second actives are loaded into a capsule.

Claim 73 (original): A method of loading an active on a bead comprising: adding the active onto one or more beads with a pharmaceutical glaze; curing the active and the glaze for between about 3 to 6 hours prior to adding a sustained release coating; and repeating the steps of adding active and curing the active at least two more times.

Claim 74 (original): The method of claim 73, wherein the active comprises a decongestant.

Claim 75 (original): The method of claim 73, wherein the active comprises phenylephrine.

Claim 76 (original): A method of providing a dual-release formulation comprising: providing a first active comprising an expectorant packed for immediate release in a powder form; providing a second active comprising a nasal decongestant packed for extended release on a bead, and enveloping the first and the second actives, wherein the first active provides productive coughs in the short-term and the second active provides long acting decongestant activity.

Claim 77 (original): A method of providing a dual-release formulation comprising: providing a first active comprising an expectorant packed for immediate release in a powder form; providing a second active comprising a nasal decongestant packed for extended release on a bead, and encapsulating the first and the second actives, wherein the first active provides productive coughs in the short-term and the second active provides long acting decongestant activity.

Claim 78 (original): A method of providing a dual-release formulation comprising: providing a first active comprising an expectorant packed for immediate release in a powder form; providing a second active comprising a nasal decongestant packed for extended release on a bead, and suspending the first and the second actives in a liquid medium, wherein the first active provides productive coughs in the short-term and the second active provides long acting decongestant activity.

Claim 79 (new): An liquid pharmaceutical composition comprising: a first active available for immediate release; and a second active coated on or about one or more suspended beads for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof, wherein the first active effects a physiological result that improves the

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physiological action of the second active upon extended release.

Claim 80 (new): The liquid pharmaceutical composition of claim 79, wherein the first and second active are made available in a solution, suspension, cream, ointment, lotion, enema, elixir, syrup, emulsion, gum, insert, jelly, foam, paste, pastille, spray, magma or poultice.